

REMARKS/COMMENTS

Reconsideration is respectfully requested. Claims 1-10, 12, 13, 15-18, 33 and 34 are pending in this application. Applicants seek to amend claims 1, 17, 33 and 34 to place the claims in better form for appeal and correct a typographical error. Claim 4 has been cancelled and part of its subject matter incorporated into independent claims 1, 17, and 34. Accordingly, no new matter has been added.

Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented, and Applicants reserve the right to prosecute the subject matter of such claims in continuation and/or divisional applications.

Claim Rejections

Under 35 U.S.C. § 102(b)

Claims 1-6, 9, 12, 15, and 17-18 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,765,983 to Takayanagi et al. In particular, the Office Action states:

“Takayanagi et al. teach a medical tape for oral mucosa comprising a support layer and a medical layer composed of a water-soluble polymer (abstract). PVP, sodium polyacrylate, and carboxyl cellulose are specified (column 2 lines 61-64). A second polymer, hydroxypropyl cellulose, is specified (column 3 lines 18-19). One or more water-soluble polymers are disclosed (column 2 line 68 column 3 line 2). Methylcellulose is specified (column 2 lines 65-66). Dissolution time may be varied by proper selection of polymers (column 3, lines 29-33): anti-inflammatory steroids are disclosed (column 2 lines 48-53). A 200 um thickness is specified (column 3, lines 15-16).”

The rejection is avoided by the amendment to claims 1 and 17.

After entry of the present amendment, the claimed invention is a pharmaceutical carrier device that includes a layered flexible film. The first layer of the film is water-erodable and contains a film-forming polymer and a bioadhesive polymer. The first layer is adhesive, and

does not incorporate a plasticizer. The second layer of the film is a water-erodable, non-adhesive backing that includes hydroxyethyl cellulose.

Takayanagi et al. teaches an adhesive medical tape having an adhesive medicament-containing layer and a support layer. Examples of polymers that the adhesive medicament-containing layer may be made from include polyvinylpyrrolidone, gelatin, polyvinyl alcohol, sodium polyacrylate, sodium carboxymethyl cellulose, starch, xanthane gum, karaya gum, sodium alginate, methyl cellulose, carboxyvinyl polymer, agar-agar and hydroxypropyl cellulose (in particular, highly substituted one (HPC-H)). The support layer may be formed from intestine-soluble polymers such as hydroxymethyl cellulose phthalate, cellulose acetate phthalate, carboxymethylethyl cellulose and poly(methacrylic acid, methylmethacrylate).

Applicants submit that, as amended, claims 1-6, 9, 12, 15, and 17-18 are not anticipated by Takayanagi et al. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). Amended claims 1 and 17 now recite that the non-adhesive backing layer includes hydroxyethyl cellulose. Takayanagi et al. do not disclose the use of hydroxyethyl cellulose in their backing (i.e., the support layer).

Based on the foregoing, Takayanagi et al. does not describe or suggest all the required claim limitations. Withdrawal of the rejection of claims 1 and 17 is respectfully requested.

Since claims 2-6, 9, 12 and 15 depend from claim 1, and claim 18 depends from claim 17, they also include the feature of including hydroxyethyl cellulose in the backing layer. Consequently, they are also not anticipated by Takayanagi et al., and the rejection of these claims is also respectfully requested.

Under 35 U.S.C. § 103(a)

Claims 1-9, 12, 15, 17-19 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,765,983 to Takayanagi et al. in view of WO 95/05416 (WO '416); and EPA 250187 (EPA '187). In particular, the Office Action states:

"WO '416 teaches overlaying an adhesive layer to prevent leakage of active from edges (page 30 lines 16-24)."

EPA '187 teach an intra-oral film (Title). Flavors are disclosed as customary (page 4, lines 41-43)."

"It would have been obvious to one of ordinary skill to overlay an adhesive layer in Takayanagi et al. to achieve the beneficial effect of preventing leakage of active from edges in view of WO '416 and to add a flavor as a customary additive in intra-oral films in view of EPA '187."

As an initial matter, Applicants assume that the rejection does not apply to claim 19 since that claim was cancelled in an amendment dated September 18, 2000. If this is incorrect, correction by the Examiner is requested.

Applicants submit that claims 1-9, 12, 15, 17-18 and 34 are not rendered obvious by Takayanagi et al. in view of WO '416 and EPA '187. To establish a *prima facie* case of obviousness, three basic criteria must be met, one of which the prior art reference (or references combined) must teach or suggest all the claim limitations. See MPEP 2143.

As discussed above, Takayanagi et al. does not teach or suggest hydroxyethyl cellulose in the backing layer. WO '416 describes a laminated device for the controlled release of a substance having a basal layer and an upper layer. The upper layer is made with hydroxypropyl cellulose. EPA '187 teaches a medicament containing film having a backing layer that contains hydroxypropyl cellulose or polyethylene oxide homopolymers. Thus, when the teachings of Takayanagi et al., WO '416 and EPA '187 are combined, they do not teach a pharmaceutical carrier device having a backing that includes hydroxyethyl cellulose.

Accordingly, since all the limitations of the independent claims (1, 17 and 34) have not been met, a *prima facie* case of obviousness has not been properly established. Withdrawal of the rejection of claims 1-9, 12, 15, 17-18, and 34 under 35 U.S.C. § 103(a) is respectfully requested.

Allowable Subject Matter

Claims 10, 13, 16, and 33 have been objected to as being dependent upon a rejected base claim but have been indicated as allowable if rewritten in independent form to include all the limitations of the base claim. Claims 10, 13, 16 and 33 depend from base claim 1, either directly

or indirectly. As elucidated above, Applicants have amended claim 1 to distinguish Takayanagi et al.

SUMMARY

Applicants have responded to each matter of substance raised in this Office Action and believe that the case is in condition for allowance. Should the Examiner have any requests, questions, or suggestions, he is invited to contact the Applicants' representative at the number listed below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 359872000821. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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